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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/712,363	11/13/2000	David Eisenberg	07419-032001 / LA99-566-6	9082

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08/13/2002

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EXAMINER

STRZELECKA, TERESA E

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 08/13/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/712,363

Applicant(s)

EISENBERG ET AL.

Examiner

Teresa E Strzelecka

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 31-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3,10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I (claims 1-30) in Paper No. 12 is acknowledged.

The traversal is on the ground(s) that:

- A) the newly added linking claim 34 ties Groups I and II, and therefore these should be examined together, since the method steps are the same, so no search burden will be added by searching these two groups together,
- B) Groups III-V should be added to groups I and II, since search for the methods will lead to the search for a computer program and computer system.

While the first part of Applicant's argument is considered persuasive, the second one concerning the computer program and a computer system is not found persuasive because restriction of related inventions is proper if it can be shown that the inventions have a different classification, or have acquired a separate status in the art or have a different field of search (see MPEP 808.02). In this case the methods of Groups I and II are different from the computer software and a computer system. Because these inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions III-V require different searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

The requirement is still deemed proper and is therefore made FINAL.

2. Therefore claims 1-30 and 34 will be examined in this Office action.
3. Claims 31-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in Paper No. 12.

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4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

5. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 1-30 and 34 of this application. Applicants claim priority to the following provisional applications: 60/117,844 (filed 01/29/1999), 60/118,206 (filed 02/01/1999), 60/126,593 (filed 03/26/1999), 60/134,092 (filed 05/14/1999), 60/134,092 (filed 05/14/1999). However, the general methodology described in those applications does not support the claims of the present application. Therefore, the earliest priority date for claims 1-30 and 34 is November 12, 1999, which is the filing date for the provisional applications 60/165,086 and 60/165,124.

Specification

6. The disclosure is objected to because of the following informalities: on page 7, line 14, there is a statement "Figure shows...", and it should refer to Figure 4.

Appropriate correction is required. No new matter should be introduced.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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8. Claims 1-30 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 34 is indefinite because of the limitation : "... nucleic acid or polypeptide sequence that may possess a property of interest functionally related to a first nucleic acid or a first polypeptide sequence..." (emphasis added). It is unclear what sequence properties are described by the term "a property of interest functionally related to a ... sequence..."

B) Claim 3 recites the limitation "the drug" in line 1. There is insufficient antecedent basis for this limitation in the claim.

C) Claim 6 recites the limitation "the microorganism" in line 1. There is insufficient antecedent basis for this limitation in the claim.

D) Claim 30 is indefinite because of the limitation "... excessive functional links...". It is unclear what "excessive link" means.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

10. Claims 34, 1-12 and 18-20 are rejected under 35 U.S.C. 102(a) as being anticipated by Pellegrini et al. (PNAS USA, vol. 96, pp. 4285-4288, April 1999; cited in the IDS).

Pellegrini et al. teach assigning protein function using a method of protein phylogenetic profiles, in which a protein sequence is compared to protein sequences from full genomes. They teach comparing E. coli RL7 (ribosomal protein), FlgL (flagellar structural protein) and HIS5

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(histidine biosynthesis protein) proteins to 16 other fully sequenced genomes, including, *Mycobacterium tuberculosis*. The phylogenetic profile method involves comparing a sequence of the protein of interest with protein sequences from other genomes and identifying genomes which code for the homologs of the protein.

Next the proteins identified in the search are clustered to determine whether they share similar profiles, and if they do, they are considered to be functionally linked (page 4285, Fig. 1). The statistical significance of an alignment score is described by the probability (P), for which a value threshold is calculated with respect to the value $1/(N \times M)$, where n is the number of proteins in the *E. coli* genome and M is the number of proteins in all other genomes (page 4285, footnote).

11. Claims 34, 2, 4, 5, 7, 8, and 21-30 are rejected under 35 U.S.C. 102(a) as being anticipated by Marcotte et al. (Science, vol. 285, pp. 751-753, July 1999).

Marcotte et al. teach detection of protein function or protein-protein interactions using a domain-fusion (Rosetta Stone) method. The method involves determination of protein interactions from sequence comparisons. Protein domain determination and the links between the domains were obtained from the protein domain database ProDom, and there were 14,899 possible links found between the 7843 domains. Then the 4290 protein sequences from *E. coli* were searched for patterns of sequence homology, and all non-homologous proteins containing the linked domains were found. The statistical significance of an alignment score is described by the probability (P), for which a value threshold is calculated with respect to the value $1/(N \times M)$, where n is the number of proteins in the *E. coli* genome and M is the number of proteins in all other genomes (page 751; page 753, Notes 5 and 6).

For each protein triplet the second and third proteins are predicted to interact because their homologs are fused in the comparison protein (Rosetta Stone protein). The examples of interacting

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proteins from *E. coli* found by the domain fusion analysis involve gyrase A and B, acetate Co-A transferase α and β , DNA polymerase III α and ϵ , histidine biosynthesis proteins HIS2 and HIS10 and γ -glutamyl phosphate reductase and glutamate-5-ionase (Fig. 1). The domain fusion method can be also used to predict protein interactions in biochemical pathways (page 752; Fig. 2). To avoid false predictions because of some ubiquitous domains (such as SH2 and SH3) domains, which are found in a large number of proteins, but do not always interact with each other, the results of Rosetta Stone linking are filtered to retain only the domains which have a few links to other domains (Fig. 4).

12. No references were found teaching or suggesting claims 13-17, but they are rejected for other reasons.

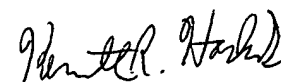
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (703) 306-5877. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

TS
August 5, 2002


KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

8/6/02